Endoscopy
Smith & Nephew, Inc.
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Andover, MA 01810 USA

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We are **smith&nephew**

MAR 1 8 2013

510(k) Summary Prepared: 7 February 2013

Submitter Information	Contact Information
Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810	Anne-Marie Keefe Senior Regulatory Affairs Specialist Phone: (508) 261-3713 Fax: (978) 749-1443

Device Name & Classification	
Proprietary Name	SUTUREFIX Ultra Suture Anchor
Common Name	Soft Tissue Fixation Device
Classification Name	Fastener, fixation, nondegradable, soft tissue
Classification Regulation	21 CFR 888.3040
Class	II
Product Code(s)	MBI
Panel	Orthopedic

Device Description

The Smith & Nephew SUTUREFIX Ultra Suture Anchor is intended to provide secure fixation of soft tissue to bone. The device consists of a soft suture anchor with an attached non-absorbable suture(s) preassembled onto an insertion device. The SUTUREFIX Ultra Suture Anchors are available pre-loaded with either one #2 suture or with two #1 sutures. This device is provided sterile, for single use only.

Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	BIORAPTOR 2.3 PK Suture Anchor	K121018	June 22, 2012
Biomet, Inc.	JuggerKnot® Soft Anchors	K110145	March 4, 2011

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Intended Use

The Smith & Nephew, Inc. SUTUREFIX Ultra Suture Anchor is intended for the secure fixation of soft tissue to bone for the following indications:

Hip

Hip capsule repair (Acetabular labrum repair/reconstruction)

Shoulder

Capsular stabilization (Bankart repair, Anterior shoulder instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstructions), Acromioclavicular separation repairs, Deltoid repairs, Rotator cuff tear repairs, Biceps tenodesis

Foot and Ankle

Hallux valgus repairs, Medial or lateral instability repairs/reconstructions, Achilles tendon repairs/reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repair/reconstructions, Bunionectomy

Elbow, Wrist, and Hand

Biceps tendon reattachment, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair

Knee

Extra-capsular repairs (Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament), Patellar realignment and tendon repairs (Vastus medialis obliquous advancement), Iliotibial band tenodesis

Technological Characteristics

The Smith & Nephew SUTUREFIX Ultra Suture Anchor is substantially equivalent in Intended Use and Fundamental Scientific Technology to the legally marked predicate devices in commercial distribution and raises no new issues of safety and efficacy.

Summary Performance Data

Performance data demonstrates that the SUTUREFIX Ultra Suture Anchor has met performance specifications for insertion strength and pull-out strength and therefore, is considered substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 18, 2013

Smith & Nephew, Incorporated
% Ms. Anne-Marie Keefe
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K122059
Trade/Device Name: SUTUREFIX Ultra Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 7, 2013
Received: February 12, 2013

Dear Ms. Keefe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known):K122059 _____

Device Name: SUTUREFIX Ultra Suture Anchor

Indications for Use:

The Smith & Nephew SUTUREFIX Ultra Suture Anchor is intended for the secure fixation of soft tissue to bone for the following indications:

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Prescription Use __X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices